

117TH CONGRESS
1ST SESSION

H. R. 4711

To amend the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 to include principal negotiating objectives of the United States relating to trade in pharmaceutical products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2021

Mr. JOYCE of Pennsylvania (for himself and Mr. BANKS) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Rules, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 to include principal negotiating objectives of the United States relating to trade in pharmaceutical products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “International Pharma-
5 ceutical Supply Chain Security Agreement Act of 2021”.

1 **SEC. 2. PRINCIPAL NEGOTIATING OBJECTIVES OF THE**
2 **UNITED STATES RELATING TO TRADE IN**
3 **COVERED PHARMACEUTICAL PRODUCTS.**

4 Section 102(b) of the Bipartisan Congressional Trade
5 Priorities and Accountability Act of 2015 (19 U.S.C.
6 4201(b)) is amended by adding at the end the following:

7 **“(23) TRADE IN COVERED PHARMACEUTICAL**
8 **PRODUCTS.—**

9 “(A) IN GENERAL.—With respect to an
10 agreement relating to trade in covered pharma-
11 ceutical products that is proposed to be entered
12 into with the United States and to which sec-
13 tion 103(b) will apply, the principal negotiating
14 objectives of the United States are the fol-
15 lowing:

16 “(i) To ensure that a party to the
17 agreement adopts and maintains measures
18 to eliminate the imposition or reimposition
19 of tariffs on imports of such products, par-
20 ticularly in the event of a declared emer-
21 gency.

22 “(ii) To ensure that a party to the
23 agreement—

24 “(I) will reduce or eliminate reg-
25 ulatory and other technical barriers in
26 the pharmaceutical sector;

1 “(II) will promote expedited ap-
2 proval of facilities for the production
3 of such products being built by busi-
4 ness enterprises that operate one or
5 more such facilities in the territory of
6 the party;

7 “(III) will promote the use of
8 good regulatory practices and stream-
9 lined regulatory review and approval
10 processes for the production of such
11 products in the territory of the party;

12 “(IV) will eliminate duplicated
13 actions and other barriers to reduce
14 the time for approvals of both facili-
15 ties and such products; and

16 “(V) will expand transparency
17 and cooperation with other parties
18 and their manufacturers, working col-
19 laboratively, to ensure regulatory
20 processes are streamlined and har-
21 monized among other parties to the
22 maximum extent possible.

23 “(iii) To prohibit export restraints
24 against parties to the agreement, particu-
25 larly in the event of a declared emergency.

1 “(iv) With respect to use of sub-
2 sidies—

3 “(I) to encourage the coordinated
4 provision of those types of subsidies
5 that are classified under World Trade
6 Organization rules as ‘non-prohibited’,
7 such as subsidies that are not contin-
8 gent on exports or import-substi-
9 tution, to incentivize manufacturing of
10 such products, including the provision
11 of grants, loans, tax incentives, and
12 guaranteed price and volume con-
13 tracts;

14 “(II) to explicitly permit, among
15 parties to the agreement, the use of
16 production subsidies to build pharma-
17 ceutical manufacturing capacity;

18 “(III) to affirm that subsidies
19 provided by parties are not intended
20 to be used primarily for export or to
21 distort trade;

22 “(IV) to affirm parties’ commit-
23 ments under the Antidumping Agree-
24 ment and the Agreement on Subsidies
25 and Countervailing Measures, includ-

“(V) to encourage notification and consultation among parties as they are considering pharmaceutical manufacturing subsidies to increase coordination and avoid creating conditions such as oversupply or market inefficiencies among the parties.

18 “(v) With respect to government pro-
19 curement—

“(II) to increase coordination between participant countries and facilitate the involvement of participant

1 countries' companies in bids to supply
2 such products; and

3 “(III) to ensure that any partici-
4 pant in the agreement that is not al-
5 ready so designated, becomes des-
6 gnated for purposes of section 301 of
7 the Trade Agreements Act of 1979
8 (19 U.S.C. 2511).

9 “(vi) With respect to trade in serv-
10 ices—

11 “(I) to obtain fair, open, and
12 transparent access to supply chain
13 services in the markets of parties to
14 the agreement, such as distribution,
15 logistics, and transportation services;

16 “(II) to ensure any restrictions
17 or regulatory requirements maintained
18 on such services are adopted and
19 maintained in a transparent and effi-
20 cient manner; and

21 “(III) to require parties to estab-
22 lish an internal process for identifying
23 restrictions or regulatory require-
24 ments that could be waived in the
25 event of a declared emergency.

1 “(vii) With respect to transparency
2 and trade facilitation—

3 “(I) to obtain commitments
4 among parties to the agreement to de-
5 velop mechanisms for sharing infor-
6 mation on pharmaceutical supply
7 chain constraints and coordinate ap-
8 proaches with parties to minimize
9 risks that could lead to supply chain
10 failures; and

11 “(II) to the extent they have not
12 done so yet, to obtain commitments
13 from parties that they will fully imple-
14 ment the obligations under the World
15 Trade Organization’s Agreement on
16 Trade Facilitation prior to the date
17 the agreement enters into force.

18 “(viii) With respect to enforcement—

19 “(I) to ensure that benefits under
20 the agreement can only be obtained by
21 parties that are fully meeting their ob-
22 ligations under the agreement;

23 “(II) to ensure that parties will
24 not bring a dispute under another

1 agreement for actions that are con-
2 sistent with the agreement; and

3 “(III) to provide a dispute settle-
4 ment mechanism comparable to the
5 dispute settlement provisions of the
6 Agreement between the United States
7 of America, the United Mexican
8 States, and Canada.

9 “(ix) To minimize the ability of par-
10 ties to the agreement to undermine the ef-
11 fectiveness of the agreement by abusing ex-
12 ceptions in the agreement by including ad-
13 ditional procedural requirements, such as
14 notification of intent to rely on an excep-
15 tion at the time an inconsistent action is
16 taken, and limiting the duration that par-
17 ticipants may rely on an exception.

18 “(B) DEFINITIONS.—In this paragraph:

19 “(i) ACTIVE PHARMACEUTICAL INGRE-
20 DIENT.—The term ‘active pharmaceutical
21 ingredient’—

22 “(I) means any component that
23 is intended to furnish pharmacological
24 activity or other direct effect in the
25 diagnosis, cure, mitigation, treatment,

1 or prevention of a disease, or to affect
2 the structure or any function of the
3 body of a human or animal; and

4 “(II) does not include—

5 “(aa) intermediates used in
6 the synthesis of a drug product;
7 or

8 “(bb) components that may
9 undergo chemical change in the
10 manufacture of a drug product
11 and be present in a drug product
12 in a modified form that is in-
13 tended to furnish such activity or
14 effect.

15 “(ii) AGREEMENT ON SUBSIDIES AND
16 COUNTERVAILING MEASURES.—The term
17 ‘Agreement on Subsidies and Counter-
18 vailing Measures’ means the agreement re-
19 ferred to in section 101(d)(12) of the Uru-
20 guay Round Agreements Act (19 U.S.C.
21 3511(d)(12)).

22 “(iii) ANTIDUMPING AGREEMENT.—
23 The term ‘Antidumping Agreement’ means
24 the Agreement on Implementation of Arti-
25 cle VI of the General Agreement on Tariffs

1 and Trade 1994 referred to in section
2 101(d)(7) of the Uruguay Round Agree-
3 ments Act (19 U.S.C. 3511(d)(7)).

4 “(iv) BIOLOGICAL PRODUCT.—The
5 term ‘biological product’ has the meaning
6 given to such term in section 351(i) of the
7 Public Health Service Act (42 U.S.C.
8 262(i)).

9 “(v) COVERED PHARMACEUTICAL
10 PRODUCT.—The term ‘covered pharma-
11 ceutical product’ means—

12 “(I) a drug (including a biologi-
13 cal product); or
14 “(II) an active pharmaceutical
15 ingredient.”.

16 **SEC. 3. REAUTHORIZATION OF TRADE AGREEMENTS AU-**
17 **THORITY.**

18 Section 103 of the Bipartisan Congressional Trade
19 Priorities and Accountability Act of 2015 (19 U.S.C.
20 4202) is amended—

21 (1) in subsection (a)—
22 (A) by striking “July 1, 2018” each place
23 it appears and inserting “July 1, 2023”; and
24 (B) by striking “July 1, 2021” each place
25 it appears and inserting “July 1, 2026”;

- 1 (2) in subsection (b)—
2 (A) by striking “July 1, 2018” each place
3 it appears and inserting “July 1, 2023”; and
4 (B) by striking “July 1, 2021” each place
5 it appears and inserting “July 1, 2026”; and
6 (3) in subsection (c)—
7 (A) by striking “July 1, 2018” each place
8 it appears and inserting “July 1, 2023”;
9 (B) by striking “June 30, 2018” and in-
10 serting “June 30, 2023”;
11 (C) in paragraph (1)(B), by striking “July
12 1, 2021” and inserting “July 1, 2026”;
13 (D) in paragraph (2), by striking “April 1,
14 2018” and inserting “April 1, 2023”; and
15 (E) in paragraph (3), by striking “June 1,
16 2018” and inserting “June 1, 2023”.

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